

### **REMARKS**

This is a full and timely response to the Office Action mailed November 15, 2006, submitted concurrently with a three month Extension of Time to extend the due date for response to May 15, 2007.

Claims 3-5 have been amended to more particularly define the present invention and to address the Examiner's rejection under 35 U.S.C. §112, second paragraph. Support for these amendments can be found variously throughout the specification and the original claims. Thus, claims 1-5 are pending in this application.

In view of this response, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the following remarks is respectfully requested.

#### **Rejection under 35 U.S.C. §112**

Claims 1-5 are rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Further, claims 1-5 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. Applicant respectfully traverses these rejections.

The Examiner has issued both of these rejections on the basis that the present specification does not contain an express definition of the term “*genetically biotinylated*” and does not teach “*how to make and genetically fuse a gene encoding a streptavidin-binding peptide to an anti VEE-scFv gene wherein the fusion antibody not only retained VEE-antigen binding specificity but also possessed streptavidin binding activity*”. The Examiner also argues that “*it is not clear from the disclosure how to use the scFv or what is involved in the reacting step between the scFv Ab and the sample containing VEE for observing antigen-binding activity*”. Based on Applicant’s review of the specification, Applicant strongly disagrees with the Examiner’s arguments in support of these rejections.

On page 6 of the specification, the disclosure **incorporates by reference** the teachings of U.S. Provisional Application No. 60/448,902 in which the present inventors **eliminate the need for chemical biotinylation** by genetically fusing a gene encoding a streptavidin-binding peptide to an anti-VEE scFv antibody gene. Applicant has enclosed, for the Examiner's convenience, the

disclosure of U.S. Provisional Application No. 60/448,902 as represented by U.S. Patent Application Publication No. U.S. 2005/0118569 which claims priority to U.S. Provisional Application No. 60/448,902. Applicant respectfully requests the Examiner to review the disclosure of U.S. Provisional Application No. 60/448,902 and in particular, the Figures and Examples contained therein. Applicant believes that the disclosure of U.S. Provisional Application No. 60/448,902 sufficiently teaches one skilled in the art the meaning of the term "*genetically biotinylated*" and set forth in detail the process of genetically fusing a gene encoding a streptavidin-binding peptide to an anti-VEE scFv antibody gene such that one skilled in the art can practice the present invention without undue experimentation.

Under §2163.07(b) of the Manual of Patent Examining Procedure, Applicant can incorporate the content of another document (in this case, U.S. Provisional Application No. 60/448,902) or part thereof by reference into the text of the specification. Under the MPEP, the Examiner must treat the information incorporated "*as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed*". Hence, it is clear that the present disclosure clearly teaches one skilled in the art (1) how to make and genetically fuse a gene encoding a streptavidin-binding peptide to an anti VEE-scFv gene wherein the fusion antibody not only retained VEE-antigen binding specificity but also possessed streptavidin binding activity and (2) how to use the scFv and what is involved in the reacting step between the scFv Ab and the sample containing VEE for observing antigen-binding activity.

Thus, for these reasons, withdrawal of this rejection is respectfully requested.

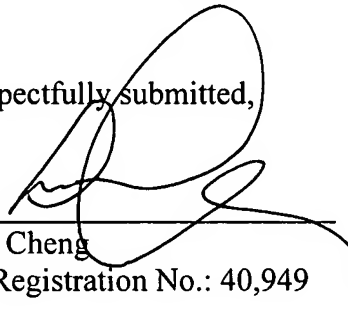
Applicant notes that to further avoid any confusion regarding the meaning of the claims, Applicant has amended claims 3-5 to clarify that the "*biotinylated scFv Ab*" and "*biotinylated antibody*" recited therein are "*genetically biotinylated scFv Ab*" and "*genetically biotinylated antibody*", respectively. Thus, Applicant believes that the Examiner's confusion in this regard has been alleviated.

### CONCLUSION

For the foregoing reasons, all of the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

Dated: May 14, 2007

Respectfully submitted,



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